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UNITED STATES OF AMERICA

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
HELENA DIVISION**

UNITED STATES OF AMERICA, Plaintiff, vs. THOMAS C. WEINER, Defendant.	CV-24-58-H-TJC RESPONSE TO DEFENDANT'S MOTION TO DISMISS
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The United States, through Assistant U.S. Attorney Michael A. Kakuk, submits this response to defendant Weiner's Motion to Dismiss. Doc. 21. Weiner's argument conflates the pleading standard on counts 1 and 2 (the False Claims Act claims) with that of counts 3 and 4 (the Controlled Substance Act claims), and he makes incorrect factual and legal arguments as to both. The

complaint here sufficiently supports all claims for relief, and Weiner’s motion to dismiss should be summarily denied.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 8(a), a complaint must be “plausible on its face.” *Bell A. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This means the complaint must contain “sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face,” or, in other words, that “allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotations omitted). At the pleading stage, the court must “accept as true all factual allegations in the operative complaint, and [must] construe them in the light most favorable to the Plaintiff as the non-moving party.” *Eichenberger v. ESPN, Inc.*, 876 F.3d 979, 981 (9th Cir. 2017).

Under Federal Rule of Civil Procedure 9(b), fraud claims also must be plead with “particularity.” This means claims for relief under the False Claims Act (FCA) must be “specific enough to give the defendant notice of the particular misconduct so that it can defend against the charge.” *Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1208 (9th Cir. 2019). It is important to note that the complaint “is not required to identify actual examples of submitted false claims” and the plaintiff “is not required to identify representative examples of

false claims to support every allegation[.]” *Id.* at 1209. Rather, “it is sufficient to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.” *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998-99 (9th Cir. 2010) (internal quotations omitted).

ARGUMENT

The United States pled sufficient facts in its complaint to survive Weiner’s motion to dismiss. Weiner attempts to set an impossibly high bar by blending all the government’s causes of action together, and by applying caselaw dealing with summary judgment, ultimate liability, or criminal statutes out of context. While the standard for a civil complaint is more than mere notice pleading, as the Ninth Circuit noted, it is still a low hurdle:

At the motion to dismiss stage, [the plaintiff’s] assessment is entitled to the presumption of truth. The standard at this stage of the litigation is not that plaintiff’s explanation must be true or even probable. The factual allegations of the complaint need only plausibly suggest an entitlement to relief.

Winter ex rel. U.S. v. Gardens Regl. Hosp. and Med. Ctr., Inc., et al., 953 F.3d 1108, 1121 (9th Cir. 2020) (internal quotations and citations omitted).

Under this correct standard, the United States’ claims are properly pled. First, the Controlled Substance Act (CSA) claims are “plausible,” especially where, as here, the subjective intent standard set forth in *Ruan v. United States*

does not apply. Second, the FCA claims are both “plausible” and plead with “particularity.” The complaint alleges facts sufficient both for the court to reasonably infer the defendant knowingly submitted false claims and to provide defendant notice of the types of claims involved.

A. The complaint sufficiently alleges civil violations of the Controlled Substances Act.

The complaint alleges that Weiner operated outside of his specialty by prescribing high levels of opioids to patients who no longer had cancer. Doc. 1, ¶ 92. For the 11 patients at issue,¹ Weiner failed to follow standard protocol for prescribing high dosage opioids, such as document any specific goals or outcomes, offer any nonpharmacologic therapy, have patients sign pain contracts, obtain any urine drug screenings, or conduct any patient pill counts. *Id.* In addition, the complaint specifically alleges that Weiner prescribed 165 MME/day to a patient with documented alcoholism and other addictive behaviors, and over 300 MME/day to a patient despite Weiner’s own written reservations with the patient’s drug-seeking behavior. *Id.*, ¶¶ 94-95. Rather than continue to note his concerns

¹ Weiner complains that he does not have the specific patients or prescriptions at issue and must “shadowbox.” Doc. 22, pg.10. But he never requested this information from the United States prior to filing his motion. More importantly, Weiner can respond to any allegation that he lacks knowledge or information, which has the effect of a denial. Fed. R. Civ. P. 8(a)(5). So, it is unclear exactly how much “shadowboxing” is required at this pleading stage.

or cease prescribing to that patient, Weiner instead choose to stop documenting his opioid prescribing at all. *Id.* These allegations demonstrate clear breaches of standard protocol as alleged in paragraphs 51-53 of the complaint (Doc. 1) and properly justify the CSA violations alleged in counts 3 and 4.

Weiner incorrectly asserts that the CSA violations “must be plead plausibly, with particularity, and as to Dr. Weiner’s subjective beliefs under both the FCA and CSA.” Doc. 22, pg. 1. This is wrong as to both the “particularity” and the “subjective belief” standards. First, no court has held that civil violations of 21 U.S.C. § 842 are subject to the “particularity” standard for fraud claims under Fed. R. Civ. P. 9(b). *See, e.g., U.S. v. Amerisource Bergen Corp.*, 2023 WL 7311183, at *3 (E.D. Pen. Nov. 6, 2023) (applying only “plausibility” test under Rule 8(a)); *U.S. v. Howen*, 2022 WL 18420744, at *4 (E.D. Cal. Aug. 9, 2022) (same); *U.S. v. Ridley’s Fam. Markets, Inc.*, 2021 WL 2322478, at *1 (D. Utah June 7, 2021) (same); *U.S. v. Appalachian Regl. Healthcare, Inc.*, 246 F. Supp. 3d 1184, 1188 (E.D. Ky. 2017) (same); *U.S. v. City Pharm., LLC*, 2016 WL 9045859, at *2 (N.D.W. Va. Dec. 19, 2016) (same).

Second, the *Ruan* decision erroneously cited by Weiner applied a subjective intent standard to criminal prosecutions under a different statute: 21 U.S.C. § 841. *Ruan v. United States*, 597 U.S. 450, 457 (2022). In *Ruan*, the U.S. Supreme Court specifically held that “§ 841’s ‘knowingly or intentionally’ *mens rea* applies

to the ‘except as authorized’ clause” in that same statute. *Id.* In contrast, the statute at issue here is 21 U.S.C. § 842(a)(1), which has no “knowingly or intentionally” clause to apply. Indeed, some courts have held that violations of 21 U.S.C. § 842(a) are strict liability offenses. *See U.S. v. Green Drugs*, 905 F.2d 694, 697-8 (3d Cir. 1990) (“a reading of the statutory text and history makes clear that Congress intended strict compliance with the recordkeeping provisions, with strict liability to attach for civil violations”).² Courts that have directly addressed this issue post-*Ruan* have universally held that the “subjective belief” requirement does not apply to civil violations of § 842(a)(1) or (a)(5). *Howen*, 2022 WL 18420744 at *7; *U.S. v. Spivak*, 2022 WL 4091669, at *1, n. 1 (E.D. Pa. Sept. 6, 2022) (explaining the differences in the statutes, and that the holding in *Ruan* is a standard of proof at trial, not a pleading standard).

Regardless, the complaint alleges facts sufficient for any *mens rea* standard the court could seek to apply. Weiner himself noted his reluctance to continue prescribing to Patient 2 because he was unsure the prescribing was medically necessary, then violated a basic standard of medical protocol by failing to record

² While 21 U.S.C. §§ 842(a)(5) and (a)(10) have since been amended to include the “negligently” standard for recordkeeping violations, it is noteworthy that Congress did not similarly include a *mens rea* element to subsections (a)(1) through (a)(4). *U.S. v. Al-Amin*, 2016 WL 744306, at *2 n. 5 (E.D. Tenn. February 23, 2016) (noting this difference).

his continued prescribing in his medical records. Taking these facts in the light most favorable to the plaintiff, Weiner stopped documenting his actions because he knew what he was doing was wrong.

Perhaps the clearest articulation of the pleading standard under Fed. R. Civ.

P. 8(a) is that two issues must be addressed:

First, to be entitled to the presumption of truth, allegations in a complaint or counterclaim may not simply recite the elements of a cause of action, but must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively. Second, the factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation.

Starr v. Baca, 652 F.3d 1202, 1216 (9th Cir. 2011). Here, the allegations of prescribing without medical necessity contain sufficient facts to give “fair notice” to Weiner and more than plausibly “suggest” the United States is entitled to relief. Anything else is simply not required in a complaint. To the extent Weiner wants all of the details of these claims, they will be provided through the normal discovery and trial processes.

B. The complaint also sufficiently alleges False Claims Act violations.

To allege an FCA violation, a complaint must show: “(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due.” *Godecke*, 937 F.3d

at 1208 (*quoting U.S. ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir 2017)). There does not appear to be any dispute that the United States has properly alleged that government health care programs paid money for claims submitted, or caused to be submitted, by Weiner (element 4). Doc. 22.

Therefore, the United States will focus on the first three elements.

1. The complaint alleges Weiner engaged in a fraudulent course of conduct and alleges enough facts with particularity to make it plausible that false claims were submitted as part of that scheme.

The complaint lays out the fraudulent scheme and identifies the types of fraudulent claims Weiner filed (or caused to be filed, through his superbills) to government health care programs. The two parts to this scheme were Weiner's double-billing of Evaluation and Management (E&M) codes and his billing for unnecessary treatment.

First, the complaint provides more detail than is strictly necessary about Weiner double-billing for office visits on the same day as other treatment. The United States cites specific examples of HCPCS codes where an office visit is already part of the payment for the code, and alleges Weiner almost always billed a second E&M office visit code the same day as the other treatment already billed. Doc. 1, ¶¶ 76-77. The complaint then explains these claims were false because there was not a "significant, separately identifiable" reason for the additional E&M billing, and/or because there was a lack of proper documentation in Weiner's

medical records. *Id.*, ¶¶ 76, 79. These facts address the “who, what, when, where, and how” of Weiner’s double-billing E&M codes. *See Goedke*, 937 F.3d at 1208.

Weiner states several times that the United States should have provided all, or at least some, specific claims that are fraudulent. Doc. 22, pgs. 3, 9-10, 19. However, Weiner’s demands are beyond what is required in a pleading; again, “[t]o state an FCA claim, a [plaintiff] is not required to identify actual examples of submitted false claims.” *Godecke*, 937 F.3d at 1209; *also see U.S. ex rel. CA Challenger LLC v. Emanate Health et al.*, 2024 WL 4868644, at *5 (C.D. Cal. Sept. 3, 2024) (“Relator’s complaint does not detail the specifics of any false medical reimbursement claims,” but was sufficiently pled); *U.S. ex rel. Garrett v. Kootenai Hosp. Dist.*, 2020 WL 3268277, at *4-5 (D. Id. June 17, 2020) (same). All that is required are “particular details” of a scheme and “reliable indicia” that creates a “strong inference” that false claims were actually submitted. *Godecke*, 937 F.3d at 1209.

Here, the “reliable indicia” that false claims were actually submitted include:

- 1) that Weiner had more patient visits in a typical day than three or more normal oncologists; 2) an outside auditor determined in 2018 that over 90% of Weiner’s E&M billing was not justified; 3) rather than change his practices, Weiner fought to have the hospital use a “dummy code” so that he would get paid the same; 4)

when that didn't work, Weiner retroactively changed his medical records to get the claims paid; and 5) Weiner's E&M billing did not decrease after the 2018 audit. Doc. 1, ¶¶ 56-59, 79-84. As in similar cases like *Godecke, CA Challenger*, and *Garret*, these facts make it plausible that false claims were submitted to the government, which is all that is required at this stage.

Second, for the false claims based on unnecessary treatment, it is well-settled that "false certification of medical necessity can give rise to FCA liability." *Winter*, 953 F.3d at 1118 (holding that medical "opinion" can be the basis for FCA claims and noting several other Circuit Court opinions holding the same). In addition to alleging lack of medical necessity, the complaint details which specific codes were billed, specifies how those codes billed by Weiner lacked medical necessity, and ties these claims together with Weiner's principal scheme to obtain more personal income by maximizing his billings. Doc. 1, ¶¶ 85-90.

Weiner's argument that these allegations are conclusory and not particularized (Doc. 22, pg. 9) ignores several facts. First, the United States identifies specific billing codes for each type of claim at issue. Doc. 1, ¶¶ 61-71. Second, the United States does not baldly state that these claims were fraudulent, but instead explains exactly how each type of claim was not medically necessary. For example, not all Rituximab treatments were fraudulent; this case involves only those claims Weiner ordered and billed for Rituximab past the medically

appropriate 1- to 2-year treatment regimen. Doc. 1, ¶ 89. Third, all of Weiner’s unnecessary treatment is part of the same scheme to increase his personal profit, and the same facts identified above support these allegations.

Again, these allegations address the “who, what, when, where, and how” questions and plausibly allege that false claims were submitted or caused to be submitted by Weiner. That is all that is required to plead an FCA violation at the beginning of a case. Weiner’s demands for the specific fraudulent claims that were part of his scheme will be met, but only through the standard expert analysis, discovery, and litigation of these issues.

2. Adequately alleging scienter is a lower bar, which the complaint easily exceeds.

The rule which requires fraud claims to be plead “with particularity” expressly excludes “malice, intent, knowledge, and other conditions of a person’s mind.” Fed. R. Civ. P. 9(b). Instead, mental states may be “alleged generally.” *Id.* However, an FCA claim must still allege that the defendant “knowingly” submitted false or fraudulent claims. *Godecke*, 937 F.3d at 1211. This *mens rea* requirement can be based on a defendant’s actual knowledge, reckless disregard, or deliberate ignorance of the truth or falsity of the claim. *Id.*

Weiner cites two cases for the proposition that scienter requirements are “rigorous” and must be strictly enforced. Doc. 22, pg. 13 (*citing Winter*, 953 F.3d

at 1117, and *Universal Health Services, Inc., v. U.S.*, 579 U.S. 176, 192 (2016)).

However, the courts in both *Winter* and *Escobar* were determining whether a specific theory of liability met the elements of an FCA claim. *Id.* Weiner conflates this “rigorous” standard required to ultimately prove an FCA violation with the standard for pleading a proper claim. While it is necessary to allege facts showing scienter is “plausible,” nothing requires a plaintiff to rigorously prove a defendant’s state of mind in a complaint.

Regardless, it is hard to imagine what more evidence of scienter could be required regarding Weiner’s double-billing of E&M codes. An outside auditor and internal coders met with Weiner and explained to Weiner why his E&M billing was inappropriate. Doc. 1, ¶ 79. After the hospital denied Weiner’s request for a “dummy code” so he could be paid the same, he went back and altered medical records to get those claims paid anyway. *Id.*, ¶¶ 81-82. Weiner’s own statements show that his intent was to get back the more than \$100,000 he had lost from the coders not submitting his inappropriate claims. *Id.*, ¶ 80. Furthermore, Weiner continued to see the same number of patients and double-bill the same E&M codes, because his E&M billing never decreased during the relevant time frame of 2018 through 2020. *Id.*, ¶ 84.

Weiner argues that these facts somehow do not tend to establish his knowledge that he should not have double-billed those E&M claims, because they

occurred “many months” prior to his submission of the alleged false claims. Doc. 22, pg. 15 (emphasis removed). This is puzzling, because it is unclear how someone could have knowledge that a claim is false without obtaining that knowledge at some point prior to submitting the claim. The very definition of knowledge—some fact, information, or skill acquired through experience or education—requires that it was gained in the past. To the extent Weiner is arguing that the United States must prove Weiner’s actual thoughts at the exact time a claim was submitted, no caselaw supports such a theory either at trial or at this pleading stage.

For the unnecessary services FCA claims, the complaint alleges for each category of claim that Weiner either knew, or he acted in deliberate ignorance or reckless disregard, that his treatment was not medically necessary. Doc. 1, ¶¶ 85-90. The complaint also alleges that these claims were part of same overarching scheme as the E&M double-billing to maximize his relative value units (RVUs). *Id.*, ¶ 85. Weiner was knowingly trying to maximize his own profit, because as Weiner himself states, “[t]he purpose of the RVU system is to monetize the work that I do[.]” *Id.*, ¶ 80.

Taking these facts in the light most favorable to the plaintiff, they allege that Weiner, an experienced doctor and the head of cancer treatment at St. Peter’s Hospital, knowingly billed for unnecessary cancer treatment in several ways.

That these treatments were within his specialized area of practice, coupled with his own statements about personal compensation from RVUs and his double-billing E&M codes, makes it more than plausible that Weiner at the very least “recklessly disregarded” or acted with “deliberate ignorance” as to the falsity of his medically unnecessary claims.

3. The falsity in Weiner’s claims was material to the government, based on statutes, regulations, and case law.

Materiality, much like scienter, is an element of an FCA claim and must be supported by allegations in the complaint. The complaint here alleges that, by statute, Medicare may only reimburse for services that are “reasonable and necessary.” Doc. 1, ¶ 21. Providers must certify that claim information is accurate and medically necessary, and providers such as Weiner are responsible for billing for services only when they are “supported by evidence of medical necessity.” *Id.*, ¶¶ 21-22. Similarly, medical necessity is a requirement for payment under Medicaid, TRICARE, and the VA medical programs. *Id.*, ¶¶ 27-28, 31-33, 37, and 39. Finally, billing CPT or HCPCS codes implies that those services meet all of the requirements of the codes billed for. *Id.*, ¶ 72.

Weiner asserts that there is “not even a ‘conclusory allegation’ that had the Government known of these violations, it would not have paid the claims[.]” Doc. 22, pg. 20. This is untrue. The complaint alleges both that the United States

“paid moneys based on those claims that otherwise would not have been paid” and that “[t]he falsity in these records was material, in that the government health care programs would not have paid the claims had they known the truth about the medical necessity of the treatment provided.” Doc. 1, ¶¶ 99, 101.

Weiner also argues that these citations to regulations and statutes are not “dispositive.” Doc. 22, pg. 19. The complaint is a pleading; nothing should be dispositive at this stage. But these allegations are sufficient to plead materiality, as “a false certification of medical necessity can be material.” *Winter*, 953 F.3d at 1122. Weiner cites *Winter* as an example of a well-pled complaint. Doc. 22, pg. 10. In *Winter*, the plaintiff highlighted “Medicare statutes and regulations” and “allege[d] that the government would not have paid Defendants’ false claims if the true facts were known.” *Winter*, 953 F. 3d at 1122 (internal quotations omitted). The Ninth Circuit declared this sufficient to plead materiality for FCA claims “at this stage of the case.” *Id.* Since this is what the United States’ complaint here alleges, no more is required.

CONCLUSION

As set forth above, the complaint provides more than adequate details to notify Weiner of the claims at issue and alleges facts that at least plausibly support the government’s claims for relief. Therefore, the Court should deny Weiner’s motion to dismiss the complaint.

DATED this 6th day of December 2024.

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CERTIFICATE OF COMPLIANCE

Pursuant to Local Rule 7.1(d)(2)(E), the attached brief is proportionately spaced, has a typeface of 14 points and contains 3,489 words, excluding the caption and certificates of service and compliance.

/s/ Michael A. Kakuk
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CERTIFICATE OF SERVICE

I hereby certify that on the 6th day of December 2024, a copy of the foregoing document was served on the following person by the following means.

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